



ASSOCIATION FOR PROFESSIONALS IN  
INFECTION CONTROL AND EPIDEMIOLOGY, INC.

March 20, 1998

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Dockets Management Branch  
(HFA-305)  
Food and Drug Administration  
12420 Parklawn Drive, Room 1-23  
Rockville, MD 20857

Dear Sir or Madam:

On behalf of the Association for Professionals in Infection Control and Epidemiology (APIC), I thank you for this opportunity to offer comment regarding the FDA's intention to review and revise compliance policy guides and regulatory requirements relating to the remarketing of used medical devices.

APIC is a multi-disciplinary, voluntary international organization, representing approximately 12,000 individual infection control professionals. APIC's mission is to promote wellness and prevent illness and infection world-wide by advancing health care epidemiology through education, collaboration, research, practice, and credentialing.

APIC shares the agency's concern for ensuring that secondarily marketed devices meet appropriate performance requirements for their intended uses, and are as safe as the originally marketed device. To this end, professionals in the infection prevention community believe that there is a legitimate need for regulation of companies that reprocess such devices labeled for single use. It is unclear from the definitions of *refurbisher*, *"as is" remarketer*, and *servicer*, however, as to whether agency standards or guidance will also apply to reprocessors.

APIC considers reprocessors to be individuals who clean and either disinfect or sterilize single-use devices for reuse. Typically, a health care facility contracts with a reprocessor to reprocess devices used within that facility for reuse within the same facility. In such cases, the facility pays a fee to the reprocessor for this service, rather than actually "repurchasing" the devices. There may be some reprocessors who purchase used single-use devices, reprocess them, and then sell or "remarket" them as well. We would certainly urge the agency to include reprocessors in any future regulation.

As you may realize, health care facilities sometimes reprocess single-use devices internally, rather than seeking such services from private companies. Since patient safety is of paramount concern, we believe that it also will be necessary to subject health care facilities engaged in reprocessing to the same quality standards applied to private companies who reprocess single-use medical devices.

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Generally, we are supportive of FDA's efforts in this area, and would be pleased to offer our assistance as the agency moves forward in revising any of its compliance policy guides. If we may offer any clinical or epidemiological expertise, we hope you will call upon our experienced membership.

I thank you again for this opportunity to comment. If you have questions or require further information, please contact Jennifer Thomas, APIC's Director of Government and Public Affairs, at 202-296-2742.

Sincerely,

A handwritten signature in cursive script that reads "Frances Slater". The signature is written in black ink and is positioned above the printed name.

Frances M. Slater, RN, BSN, MBA, CIC  
APIC 1998 President

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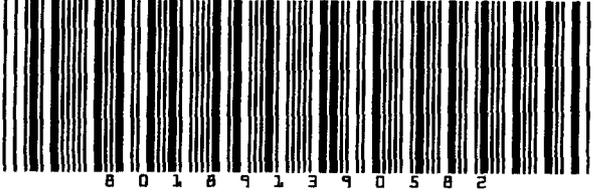
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